

BUR-020

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant: R. R. Burch et al. : Art Unit: 1615
Serial No.: 09/245,625 : Examiner: T. Ware

FOR: CHEMICALLY ACTIVE FIBER
COMPOSITIONS AS DELIVERY
SYSTEM FOR CHEMOTHERAPEUTIC
AGENTS, ESPECIALLY FOR
SUBSTANCES USEFUL IN DENTAL
HYGIENE

APPELLANTS' REPLY BRIEF UNDER 37 C.F.R. § 1.193(b)(1)

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This brief is in response to the Examiner's Answer, mailed December 14, 2001.

APPELLANTS RESPONSE

SUMMARY

For the reasons discussed in their Appeal Brief, appellants submit that (a) the Examiner has not made the *prima facie* case, and, further, (b) appellants have submitted convincing evidence of nonobviousness.

A. Grouping of Claims

The Examiner does not agree to the Grouping of Claims. In particular, the Examiner argues that "[a]ll the claims require the same elastomeric fiber imbibed with a chemotherapeutic agent." Examiner's Answer, page 3, lines 3-4. This is

incorrect.

The claims of Group II, Group III, and Group IV each recite additional limitations for the elastomeric fiber. Thus, they do not recite "the same elastomeric fiber." In the claims of Group V and Group VI, the chemotherapeutic agent is a specific chemotherapeutic agent, fluoride.

As required by 37 CFR 192 § (c)(7), appellants pointed out in the argument under 37 CFR 192 § (c)(8) "why the claims of each group are believed to be separately patentable." The Examiner argues the "appellant is merely pointing out the differences in what the claims cover...." Examiner's Answer, page 2, lines 19-20.

The Examiner fails to appreciate that it is these differences in scope, *i.e.*, "the differences in what the claims cover," that make the claims of Groups II-VI separately patentable. Each Group of claims was independently discussed in appellants' Appeal Brief. The significant additional limitations of each group were pointed out, and the reason or reasons that the claims of each Group were separately patentable over the applied references discussed. These discussions can be found in the following passages of appellants' Appeal Brief, all of which are incorporated herein by reference:

For the claims of Group II - page 12, lines 13-22

For the claims of Group III - page 12, line 23, to page 13, line 7.

For the claims of Group IV - page 13, lines 8-23.

For the claims of Group V - page 13, line 24, to page 15, line 2.

For the claims of Group VI - page 15, lines 3-15.

B. Why the Examiner Has Not Made the *Prima Facie* Case

1. The References Cannot Be Combined

In their Appeal Brief, appellants pointed out that Hill taught away from

absorbing the ingredients in the dental floss and, thus, taught away from appellants' invention. *See, Appellants' Appeal Brief, Sect. E.1(c), pages 10-12.* In particular, Hill taught that it was "critical" that the chemotherapeutic agents be loaded in the interstitial spaces of the floss. *See, Hill, column 19, line 39, to column 20, line 11.* Thus, the person of ordinary skill in the art, wanting to produce a dental floss comprising a chemotherapeutic agent and having the advantage of the teachings of Hill would not be motivated to imbibe or absorb a chemotherapeutic agent into the floss.

The Examiner has not responded to this. The Examiner has not challenged that Hill teaches away from the invention or explained why Hill does not teach away from the invention.

A reference that teaches away from an invention cannot make it obvious *In re Grasselli*, 218 USPQ 769, 779 (Fed. Cir. 1983); MPEP 2145. The rejection of claims 1-22 and 25-29 under 35 U.S.C. § 103(a) as unpatentable over Burch, in view of Hill should be reversed.

2. *The Combination of the References Does Not Produce Appellants Invention Because It Relies on Unsupported Assertions of Fact*

In their Appeal Brief, Appellants pointed out that "Hill discloses a dental floss in which the composition released by the floss is loaded in the interstitial spaces between the fibers of a dental floss. In the invention recited in appellants' claims, a therapeutically effective amount of a chemotherapeutic agent is imbibed in the fiber." Appeal Brief, page 7, lines 3-6. Thus, even if Burch and Hill could be combined in the manner indicated by the Examiner, the combination did not produce appellants' invention.

To overcome this obvious deficiency in his alleged *prima facie* case, the Examiner argues that:

It is well-known that fibers are made up of many individual strands. Imbibing is equivalent to coating unless a specific fiber size is recited as the therapeutic agent coats the multiple individual fiber strands within the unit as a whole. Indeed, page 4 of the instant specification provides a unit that is made up of multiple fibers.

Examiner's Answer, page 4, lines 16-20 (emphasis added).

The Examiner asserts that " Imbibing is equivalent to coating unless a specific fiber size is recited as the therapeutic agent coats the multiple individual fiber." There is no evidence of record to support the assertion that imbibing is equivalent to coating.

Next, the Examiner asserts that it is "well-known" that fibers are made up of many individual strands. From the context, appellants believe that the Examiner is asserting that it is well known that dental floss is inherently multi-stranded.

In support of this assertion, the Examiner points to page 4 of the specification. Page 4, in fact discloses that the fiber has a core "preferably selected from the group consisting of primary monofilament, primary multifilament, primary coalesced monofilament, and combinations thereof" and, optionally, a coating of a "secondary filament may be a secondary monofilament, secondary multifilament, spun filament, or a combination thereof." Specification, page 4, lines 13-23.

Burch discloses a dental floss which may be a monofilament (column 8, lines 8-10) or in which a multiplicity of monofilaments may be "coalesced into one primary coalesced monofilament (column 8, lines 19-30). *See also*, Burch, Figures 2 and 8. Note that Figure 3 of Burch shows a multiplicity of monofilaments that may be "coalesced into one primary coalesced monofilament" (column 8, lines 19-30). Thus, the evidence of record discloses a monofilament dental floss, contradicting the assertion that dental floss is inherently multi-stranded.

In addition, appellants' claims do not recite a dental floss that comprises

multiple strands. Claim 1 recites a fiber with a therapeutically effective amount of the chemotherapeutic agent imbibed in the fiber. Thus, the Examiner's argument relies on limitations that are not found in the claims. *See, Examiner's Answer, page 5, lines 19-22.* This is improper. *See, Intel Corp. v. U.S. Int'l Trade Comm.* 20 USPQ 2d 1161, 1174 (Fed. Cir. 1991) ("Where a specification does not require a limitation, that limitation should not be read from the specification into the claims.") (emphasis original)(citing cases).

Further, the Examiner assets that the "specific fiber size" should be recited in the claims. Claims 4-9, 12, 13, 17, 18, 20-22, and 25-29 recite a denier value for the fiber. Denier is the weight in grams of 9,000 meters of fiber. In the textile art, denier is typically used instead of diameter to indicate the fineness of the fiber. *See, for example, Hill, column 22, line 31.* Appellants submit that those skilled in the art would readily understand a fiber size from the denier range recited in these claims.

The Examiner describes the dental floss of Hill as having "drug containing filaments," thus obscuring the fact that the composition released by Hill's dental floss is loaded in the interstitial spaces between the fibers of the floss. *See, Examiner's Answer, page 5, line 21.* This is incorrect. In Hill, the composition is not "contained" in the fiber; it is coated on the surface.

The Examiner's alleged *prima facie* case depends on unsupported assertions of fact, one of which is actually contradicted by the record. This is improper. *In re Sang-Su Lee, Docket 00-1158, -- USPQ2d -- (Fed. Cir. 2002)* ("Conclusory statements ...do not fulfill the agency's obligation."). The rejection of claims 1-22 and 25-29 under 35 U.S.C. § 103(a) as unpatentable over Burch, in view of Hill should be reversed.

3. *There is no Motivation to Combine the References*

The Examiner argues that:

Accordingly, it would have been obvious to one skilled in the art at the time the of the invention to combine the teachings of [Burch] and [Hill] with the expectation of success, since both the floss of [Burch] and [Hill] utilize polymer fibers in the form of multiple strands or filaments, and the motivation that the antimicrobial agents of [Hill] would impart antimicrobial properties to the fibers of [Burch] thereby providing an effective means to deliver there microbial agents to the oral cavity or gingiva and that such a floss would accommodate and clean the spacings of different dimensions between teeth while maintaining strength.

Examiner's Answer, page 4, lines 5-12.

As discussed above, Burch discloses a dental floss which may be a monofilament (column 8, lines 8-10) or in which a multiplicity of monofilaments may be "coalesced into one primary coalesced monofilament" (column 8, lines 19-30). Thus, the Examiner's statement of motivation, that both Burch and Hill "utilize polymer fibers in the form of multiple strands or filaments," is incorrect.

The Examiner has shown no motivation to combine the references. "Omission of a relevant factor required by precedent is both legal error and arbitrary agency action." *In re Sang-Su Lee*, Docket 00-1158, -- USPQ2d -- (Fed. Cir. 2002). The rejection of claims 1-22 and 25-29 under 35 U.S.C. § 103(a) as unpatentable over Burch, in view of Hill should be reversed.

4. *There is no reasonable expectation of success from the combination of Burch and Hill*

In their Appeal Brief, appellants pointed out that Burch discloses an elastomeric dental floss and Hill discloses dental floss of "natural and/or synthetic fibers and mixtures thereof including cotton, silk, polyester and nylon." Appeal Brief, page 9, lines 25. Because the physical properties of these materials were quite different, the person of ordinary skill in art would have no reasonable expectation of success in substituting the elastomeric polymer of Burch for the non-

elastomeric polymers of Hill.

The Examiner has not responded directly to this point. The only rational for combining the references offered by the Examiner is the one quoted above, that both references disclosed multi-stranded dental floss.

Appellants submit that the physical properties of the polymer are far more important to one of ordinary skill in the art than are the number of strands in the dental floss. The person of ordinary skill in the art would be guided by the chemical structure of the polymer not by its physical form. The rejection of claims 1-22 and 25-29 as unpatentable over the combination of Burch and Hill should be reversed.

D. Appellants Have Presented Evidence of Nonobviousness

In their Appeal Brief, appellants pointed out that Example 1 of the specification shows that a spandex fiber takes up 2300 ppm of fluoride. Comparative Example 1 shows that a conventional dental floss takes up 385 ppm of fluoride. As an additional comparison, as noted in Comparative Example 1, J. Jøgensen, *et al.*, Pediatric Dentistry, 11(1), 17-20 (1989) (of record) report uptakes of 201 ± 19 ppm and 248 ± 17 ppm of fluoride when a conventional dental floss was immersed in fluoride-containing dental products.

The Examiner has dismissed appellants' evidence of non-obviousness with the statement that "the scope of the claims is not commensurate with the scope of example 1." Reply Brief, page 5, lines 14-16.

This example was not cited as evidence of the non-obviousness of all the claims.¹ It was cited as evidence of the non-obviousness, and consequently the

¹Throughout prosecution the Examiner has only considered the patentability of claim 1. *See*, for example, Examiner's Answer, § 7, page 2, line 14, to page 3, line 4. The Examiner has never considered appellants' evidence of non-obviousness with respect to the patentability of the claims of Group V and Group VI.

separate patentability, of the claims of Group V and Group VI. The claims of Group V recite that the fiber comprises at least about 1,000 ppm of water soluble fluoride. The claims of Group VI recite that the fiber comprises at least about 2,000 ppm of water soluble fluoride.

The Examiner also argues that:

However, it is unknown whether the "conventional dental floss" compared in Example 1 is the same dental floss of [Hill]. Therefore, it is unclear whether the spandex dental floss would absorb more fluoride than the dental floss of [Hill]. Indeed, [Hill] teaches that the floss disclosed therein provides for floss having surprisingly high concentrations of drug and the amount of active agent loaded is effective to treat diseases [citations omitted]. Applicants (sic) have submitted that there is no evidence that the nylon used by [Hill] differs from the nylon used in other dental floss. However, [Hill] states that it is the construction of the dental floss or how the fibers are twisted into the finished floss that influences the amount of the compositions that can be loaded into the floss of [Hill].

Examiner's Answer, page 5, lines 3-13 (emphasis added).

The factors cited by the Examiner are irrelevant. As has been discussed above and in detail in appellant's Appeal Brief, Hill loads the active agent in the interstitial spaces between the fibers of a dental floss. Thus, the amount of material that can be loaded into the interstitial spaces of Hill's dental floss will be affected by the construction of the dental floss and how the fibers are twisted into the finished floss as these factors would affect the size of the interstitial spaces. Appellants do not load chemotherapeutic agent into interstitial spaces of a twisted fiber so the manner in which the fibers are twisted is irrelevant.

Hill discloses "bonded nylon" (Hill, Table II), "unwaxed nylon" (Hill, Table III), and "white nylon unbonded floss" (Hill, column 22, line 30). Appellants reiterate that there is no evidence that the dental floss of Hill differs from

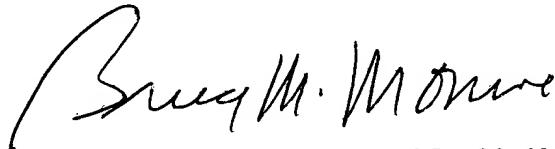
conventional dental floss.

E. Conclusion

As discussed above, the Examiner has not made the *prima facie* case. It is unchallenged that Hill teaches away from the invention. Thus, the applied references may not be combined in the manner proposed by the Examiner. Even if combined, the applied references do not suggest appellants invention because the alleged *prima facie* case depends on assertions not supported by the record. Further, with respect to the claims of Group V and Group VI, appellants have presented objective evidence of non-obviousness, which the Examiner has not considered.

The rejection of claims 1-22 and 25-29 under 35 U.S.C. § 103(a) as unpatentable over Burch, U.S. Pat. No. 5,433,266, in view of Hill, U.S. Pat. No. 5,098, 711, should be reversed, and such action is earnestly solicited.

Respectfully submitted,



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